

1616 N. Fort Myer Drive 11th Floor Arlington, Virginia 22209 USA Tel: 703-528-7474 Fax: 703-528-7480 Web: deliver.jsi.com

John Snow, Inc.

CAPILLUS HIV-1/HIV-2 RAPID TEST KIT

Brand and Manufacturer

- Capillus HIV-1/HIV-2 Rapid Test Kit
- Trinity Biotech
 P.O. Box 1059
 Jamestown, NY 04702-1059

Tel: +1 716-483-3851 Fax: +1 716-488-1990 www.trinitybiotech.com

Kit Contents

- Latex reagent (4 ml or 2 x 6.3 ml)
- Positive control (0.4 ml)
- Negative control (0.4 ml)
- 20/100 disposable pipette tips
- 1 pipette
- 1 Interpretation station

Percent Accuracy

- Sensitivity: 98.6-99.9%
- Specificity: 98.2–99.6%

Types of Samples

■ Serum, plasma, or whole blood

Run Time of Test

■ 7 minutes

Packaging Information

- 100 tests per kit
- 30 kits per carton of 100 tests (3,000 tests)

Test Kit Package

Dimensions:

7.8 x 13.5 x 22 cm

Volume:

2,316.6 cm³

Weight:

550q

Shipping Carton

Dimensions:

Volume:

69,498 cm³

Weight:

16.5 kg

Storage Conditions

- Storage temperature: 2-8°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: **9–12 months**
- Disposal Methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

The positive and negative controls should be run at least once per test day.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

- Disposable gloves
- Biohazard discard bags
- Blood collection devices

- Approximately U.S.\$1.10-2.79 per test
- Price varies according to the quantity being procured.





Logistics for Healt Program Product?

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John Snow, Inc.

DETERMINE HIV-1/2 RAPID TEST KIT

Brand and Manufacturer

- Determine HIV 1/2 Rapid Test Kit 100 tests per kit
- Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064-3500 USA

Tel: +1 847-937-6100 www.abbott.com

Kit Contents

- 100 tests per card
- Serum/plasma assay contains 10 cards
- Whole blood assay contains 10 cards and 1 bottle of chase buffer (2.5 ml)

Percent Accuracy

Sensitivity: 97.9-100%

Specificity: 100%

Types of Samples

- Serum/plasma kit
- Whole blood kit

Run Time of Test

15 minutes

Packaging Information

- Kits of 20 tests are available in some countries.

Test Kit Package

Dimensions: $27 \times 16 \times 1 \text{ cm}$

Volume: 432 cm³

Weight: 500 g

Shipping Carton

There is no standard shipping carton. The quantity is tailored to the customer's needs.

Volume: 432 cm³ x number of kits

Weight: 500 g x number of kits

Storage Conditions

- Storage temperature: 2-30°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Shelf Life and Disposal

- Shelf life: 12-18 months
- Disposal Methods:
 - Autoclave @121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they are capable of transmitting infection.

Quality Control

A procedural control is incorporated in the device. If the control bar does not turn red by assay completion, the test result is invalid and the sample should be retested.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Protective wrappers torn or discolored
- Labeling incorrect, missing, or illegible (especially product, brand, or manufactuer's name; lot and batch numbers: and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided

- Serum/Plasma Assay
 - Pipette
 - Pipette tips
- Whole Blood Assay
 - Lancets
 - EDTA capillary tubes

- Approximately U.S.\$1.20-1.50 per test
- The price varies according to the quantity being procured.





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JSI John Snow, Inc.

DOUBLECHECK HIV 1&2 RAPID TEST KIT

Brand and Manufacturer

- DoubleCheck HIV 1&2 Rapid Test Kit
- Orgenics Ltd.
 North Industrial Zone
 POB 360, 70650
 Yavne, Israel
 Tel: 972-8-9429201
 Fax: 972-8-9438758

www.orgenics.com

Kit Contents

- 40 test devices
- 42 disposable pipettes
- 42 microtubes
- 1 bottle specimen diluent (5 ml)
- 1 bottle HIV antigens (15 ml)
- 1 bottle conjugate (5 ml)
- 1 bottle chromogenic substrate (50 ml)
- 1 bottle DoubleCheck Enhancer (5 ml)
- 1 bottle stop solution (50 ml)
- 1 vial positive control (1.5 ml)
- 1 vial negative control (1.5 ml)

Percent Accuracy

- Sensitivity: 100%
- Specificity: 99.3–100%

Types of Samples

Serum and plasma

Run Time of Test

■ 10 minutes

Packaging Information

- 40 tests per kit
- 18 kits per carton (720 tests)

Test Kit Package

Dimensions: 26 x 19 x 14 cm

Volume: 6,916 cm³

Weight: 0.8 g

Shipping Carton

Dimensions: 59 x 45 x 54 cm

Volume: 143,370 cm³

Weight: approximately 14.4 kg

Storage Conditions

- Storage temperature: 4-8°C
- Do not freeze.
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Shelf Life and Disposal

- Shelf life: 12-15 months
- Dispose in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

■ Each test result is validated by an internal control.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

- Biohazard waste containers
- Timer or stopwatch
- Disposable gloves

- Approximately U.S.\$1.35 per test
- Price varies according to the quantity being procured.





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John Snow, Inc.

ENZYGNOST ANTI-HIV 1/2 PLUS: ELISA TEST KIT

Brand and Manufacturer

- Enzygnost Anti-HIV 1/2 Plus
- Dade Behring Inc. 1717 Deerfield Rd. Deerfield, Illinois 60015 USA Tel: +1 847-267-5300 Fax: +1 847-267-1066 www.dadebehring.com

Kit Contents

- Kits of 192 tests contain 2 plates of 96 tests.
- Kits of 960 tests contain 10 plates of 96 tests.
- Kits of 960 tests contain:
 - Test plates
 - HIV Aq/POD conjugate
 - Sample buffer
 - Control serum, positive
 - Control serum, negative
 - Washing solution
 - Buffer substrate
 - Chromogen
 - Stopping solution
 - Adhesive foils
 - Polyethylene bag
- Enzygnost TMB reagent supplies are not included with the 192 test kit, and need to be ordered separately. The reagent kit includes washing solution, buffer/substrate, chromogen, and stopping solution. One reagent kit is sufficient for 4 kits of 192 tests.

Percent Accuracy

- Sensitivity: 99.6-100%
- Specificity: 98.7–100%

Types of Samples

Serum and plasma (must separate from whole blood)

Run Time of Test

30 minutes

Packaging Information

- 192 or 960 tests per kit
- 25 kits per carton

Test Kit Package

Dimensions:

18 x 17.5 x 11.5 cm (192 tests)

Volume:

3.622.5 cm³ (192 tests) 18,112.5 cm³ (960 tests)

Weight:

Shipping Carton

Dimensions:

Volume:

Weight:

Storage Conditions

- Storage temperature: 2-8°C
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Shelf Life and Disposal

- Shelf life: 5 months
- Disposal Methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

6 per test run

Indicators of Potential **Quality Problems**

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided

Piston-type pipettes (25, 100, and 1000 µL)

- Approximately U.S.\$0.45-0.80 per test
- Price varies according to the quantity being procured.



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JSI John Snow, Inc.

GENIE II HIV1/HIV2

Brand and Manufacturer

- Genie II HIV1/HIV2 Rapid Enzyme Immunoassay
- Bio-Rad Laboratories
 Clinical Diagnostics
 4000 Alfred Nobel Drive
 Hercules, CA 94547 USA
 Tel: 1-800-2-BIORAD
 Fax: +1 510-741-6373
 www.bio-rad.com

Kit Contents

- 40 Genie II HIV-1/HIV-2 Reaction Devices
- 42 microtubes for diluting specimens
- 1 bottle specimen diluent (7 ml)
- 1 bottle Streptavidin/AP conjugate (7 ml)
- 1 bottle washing solution (50 ml)
- 1 bottle chromogenic substrate (5 ml)
- 1 bottle stop solution (50 ml)
- 1 vial positive control (0.5 ml)
- 1 vial negative control (0.5 ml)

Percent Accuracy

Sensitivity: 97.8–100%

■ Specificity: 99.7–100%

Types of Samples

Serum or plasma

Run Time of Test

■ 10 minutes

Packaging Information

■ 40 tests per kit

Test Kit Package

Dimensions: 26 x 18.5 x 14 cm

Volume: 6,700 cm³

Weight: 1.01 kg

Shipping Carton

No standard carton. Carton size will be chosen depending on the number of kits to delivered.

Storage Conditions

- Storage temperature: 2-8°C
- Do not freeze test kits.
- Prior to testing bring all reagents, reaction devices, and samples to room temperature (3 hours at 22–26°C or 15 minutes at 37°C).
- After testing, return remaining control solutions, reagents, and the instructions for use to the original kit box and return to cold storage (2-8°C).
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: 12 months
- Dispose in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

- Internal control spot for validation of the test procedure.
- Positive and negative controls for validation of an assay series.
- Run the positive and negative controls provided with the kit each day the test is performed, and/or when a new kit number is used.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

Disposable gloves

- Approximately U.S.\$3.00-5.00 per test
- Price varies according to the quantity being procured.





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HEMA-STRIP HIV-1/2 RAPID TEST KIT

Brand and Manufacturer

- Hema-Strip HIV-1/2 Rapid Test Kit
- Saliva Diagnostics Systems (SDS)
 3661 Horseblock Road
 Suite E
 Medford, NY 11763 USA
 Tel: +1 917-853-6440
 Fax: +1 212-937-3801
 Email: info@salv.com
 www.salv.com

Kit Contents

Each pouch contains:

- 1 sampler with a test strip
- 1 buffer vial attached to a sampler
- 1 lancet
- 1 bandage
- 1 desiccant (drying agent)

Percent Accuracy

- Sensitivity: 99.2%
- Specificity: 100%

Types of Samples

Serum, plasma, or whole blood

Run Time of Test

15 minutes



Packaging Information

- 25 pouches and 1 product insert per kit
- 25 kits per carton (625 tests)

Test Kit Package

Dimensions: 24.1 x 15.9 x 8.3 cm

Volume: 3,162 cm³

Weight: Approximately 45.3 g

Shipping Carton

Dimensions: 53.3 x 43.2 x 43.2 cm

Volume: 99,453 cm³

Weight: 11.8 kg

Storage Conditions

- Storage temperature: 20-33°C
- If the test is stored below 20°C it should be allowed to come to room temperature prior to use.
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: 15 months
- Disposal Methods:
 - Autoclave @121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes, as though they could transmit infection.

Quality Control

A pink/purple colored line should always appear in the control area if the test has been performed correctly and the device is working properly. It serves as an internal procedural control. A clear background in the test area is an internal negative procedural control.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or date of manufacture)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

- 1 clock, watch, or other timing device
- Rack for holding buffer vials upright
- Lab pipette to deliver 2.5μL sample (for serum and plasma samples only)

- Approximately U.S.\$3.00 per test
- Price varies according to the quantity being procured.





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MEDMIRA MIRAWELL RAPID HIV TEST KIT

Brand and Manufacturer

- MedMira MiraWell Rapid HIV Test Kit
- MedMira Inc.

155 Chain Lake Drive, Suite 1 Halifax, Nova Scotia B3S 1B3 Canada

Tel: 1+902-450-1588 Fax: 1+902-450-1580 www.medmira.ca

Kit Contents

The test kit is available in two formats: one for serum/plasma specimens and another for whole blood specimens.

Each test kit contains:

- 1 large foil pack containing 50 test cartridges. (Cartridges for the whole blood test format contain a pre-fitted filter unit for whole blood separation.)
- 1 small foil pack containing 50 colloidal gold-protein A conjugate caps.
- 30 ml squeeze bottle of Universal Buffer solution.
- 50 disposable transfer pipettes.
- **200** μ positive control.
- 200 μ negative control.

Percent Accuracy

- Sensitivity: 99.75-100%
- Specificity: 99.31%

Types of Samples

Serum, plasma, and whole blood

Run Time of Test

3 minutes

Packaging Information

- 50 tests per kit
- 10 kits per carton (500 tests)

Test Kit Package

Dimensions: 37.5 x 28.8 x 10 cm

Volume: 10,800 cm³

Weight: 1.05 kg

Shipping Carton

Dimensions: 55 x 37.5 x 50 cm

Volume: 103,125 cm³

Weight: 10.55 kg

Storage Conditions

- Storage temperature: 2-30°C
- Do not freeze.
- Keep test components in sealed pouches until ready to be used.
- Store in a dry area protected from direct sunlight, heat, and moisture.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Shelf Life and Disposal

- Shelf life: 12 months
- Disposal Methods:
- Autoclave @121°C for 60 minutes
- Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

- Each test result is validated by an internal control.
- Additionally, one set of controls is recommended for every 10 tests done. However, if testing more than 50 specimens per session, controls should be run at least twice for each of the 50-test packs used.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

- Disposable gloves
- Biohazard waste disposal bags
- Disinfectant solution
- Discard container
- Centrifuge (for serum/plasma preparation)

Estimated Price

- U.S.\$10.00 per test (30% discount for endusers in developing countries).
- Price varies according to the quantity being procured.



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John Snow, Inc.

MULTISPOT HIV-1/HIV-2 RAPID TEST KIT

Brand and Manufacturer

- Multispot HIV-1/HIV-2 Rapid Test Kit
- Bio-Rad Laboratories
 Clinical Diagnostics
 4000 Alfred Nobel Drive
 Hercules, CA 94547 USA
 Tel: 1-800-2-BIORAD
 Fax: +1 510-741-6373
 www.bio-rad.com

Kit Contents

- 1 test cartridge (50 tests)
- 1 bottle positive control (1 ml)
- 1 bottle negative control (1 ml)
- 1 bottle specimen diluent (25 ml)
- 1 bottle conjugate reagent (9.5 ml)
- 2 bottles wash solution (2 x 85 ml)
- 1 bottle development reagent (8.5 ml)
- 1 bottle stop solution (55 ml)
- 50 disposable transfer pipettes

Percent Accuracy

■ Sensitivity: 99.3–100%

Specificity: 98.5–100%

Types of Samples

Serum or plasma

Run Time of Test

■ 10 minutes

Packaging Information

■ 50 tests per kit

Test Kit Package

Dimensions: 14.5 x 20.4 x 19.5 cm

Volume: 5,768 cm³

Weight: 1.265 kg

Shipping Carton

Dimensions:

Volume:

Weight:

Storage Conditions

- Storage temperature: 2°-8°C
- Bring all reagents and test components to room temperature (20–30°C) before use.
 Return the entire kit to 2–8°C when not in use.
- Do not freeze test components.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: 12 months
- Disposal Methods:
 - Autoclave @121°C for 60 minutes
 - Disposable materials may be incinerated.
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

■ The positive and negative control provided with the kit should be run each day the test is performed and/or when a new kit lot number is used.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

- Disposable glass or plastic test tubes to prepare diluted specimens (ex. twelve 75 mm tubes)
- Test tube racks
- Absorbent pads or paper towels
- Biohazard bags with closures
- Bleach or other disinfectant
- Disposable gloves

- Approximately U.S.\$4.00 per test
- Price varies according to the quantity being procured.





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ORAQUICK RAPID HIV-1 ANTIBODY TEST

Brand and Manufacturer

OraQuick® Rapid HIV-1 Antibody Test

■ OraSure Technologies, Inc. 150 Webster Street Bethlehem, PA 18015 USA Tel: +1 800-869-3538 Fax: +1 610-882-2275 www.orasure.com

Kit Contents

- The 100 test kit contains 100 test devices, 105 loops, 10 test stands, 1 product insert, 100 information pamphlets, and 1 customer letter.
- The 25 test kit contains 25 test devices, 30 loops, 6 test stands, 1 product insert, 25 information pamphlets, and 1 customer letter.
- Test kit controls are required to conduct the test and are available separately. The positive and negative controls are packaged in 0.2 mL vials.

Percent Accuracy

Sensitivity: 99.6%

■ Specificity: 100%

Type(s) of Samples

Fingerstick whole blood

Run Time of Test

20 minutes

Note: OraQuick was approved by the FDA in November 2002. This fact sheet contains the current specifications of the FDA approved product. Prior to FDA approval, OraQuick was sold with different specifications for shelf life and types of samples. It is expected that specifications of the FDA approved product will be expanded as the results of ongoing tests are confirmed.

Packaging Information

- Tests are packaged in individual pouches. Each pouch contains one test.
- Tests are available in quantities of 25 and 100.

Test Kit Package

Dimensions: 15.2 x 16.5 cm

Weight: 17 q

Shipping Carton

Dimensions:

41 x 31 x 23 cm (100 tests) 31 x 23 x 15 cm (25 tests)

Volume:

29,223 cm³ (100 tests) 10,695 cm³ (25 tests)

Weight:

2.54 kg (100 tests) 0.907 kg (25 tests)

Storage Conditions

- Storage temperature: 2-27°C
- If the test is refrigerated, ensure that the pouch is brought to ambient temperature (15-27°C) before opening.
- Do not open the pouch until you are ready to perform a test.
- Store away from extreme heat. Do not store close to radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: 7 months
- Dispose of in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes, as though they could transmit infection.

Quality Control

- A control line in the 'C' area of the result window indicates a valid result. The control line will appear on all valid tests, whether or not the result is reactive.
- Kit controls should be run once per shift and whenever changing to a different lot of tests.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

Materials Required but Not Provided

- Timer or watch
- Antiseptic wipes
- Sterile lancets
- Sterile gauze pads
- Disposable gloves
- Biohazard disposal container

Estimated Price

- U.S.\$3.00/test for bulk purchases outside the U.S.
- Prices will vary according to the quantity being procured.





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SEROCARD HIV RAPID TEST KIT

Brand and Manufacturer

SeroCard HIV Rapid Test Kit

Trinity Biotech

P.O. Box 1059 Jamestown, NY 04702-1059 USA

Tel: +1 716-483-3851 Fax: +1 716-488-1990 www.trinitybiotech.com

Kit Contents

- 20 packages, each containing 2 test cards (40 tests)
- Enzyme conjugate reagent (5 ml)
- BCIP substrate reagent (8 ml)
- Wash reagent (24 ml)
- 40 disposable pipettes

Percent Accuracy

- Sensitivity: 99.8–100%
- Specificity: 97.9–99.5%

Types of Samples

Whole blood, serum, or plasma

Run Time of Test

5 minutes

Packaging Information

■ 40 tests per kit

Test Kit Package

Dimensions:

Volume: cm3

Weight:

Shipping Carton

Dimensions:

Volume: cm³

Weight:

Storage Conditions

- Storage temperature: 2-8°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Quality Control

The SeroCard assay has a nonspecific binding reaction port to confirm that only HIV specific antibodies are present.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Protective wrappers torn or discolored
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided

- Timer or stopwatch
- Blood collection devices

Shelf Life and Disposal

- Shelf life: 9 months
- Disposal Methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

- Approximately U.S.\$1.80
- Price varies according to the quantity being procured.







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UNI-GOLD HIV TEST

Brand and Manufacturer

- Uni-Gold HIV Rapid Test Kit
- Trinity Biotech
 P.O. Box 1059
 Jamestown, NY 04702-1059

USA

Tel: +1 716-483-3851 Fax: +1 716-488-1990 www.trinitybiotech.com

Kit Contents

- 20 test devices
- Wash reagent (2 ml)
- 20 disposable pipettes
- 1 package insert

Percent Accuracy

- Sensitivity: 99.6–100%
- Specificity: 98.7-100%

Types of Samples

Serum, plasma, or whole blood

Run Time of Test

■ 10 minutes

Packaging Information

- 20 tests per kit
- 100 or 150 kits per carton (2,000 or 3,000 tests)

Test Kit Package

Dimensions: 23 x 14 x 10.5 cm

Volume: 3,381 cm³

Weight: approximately 300 g

Shipping Carton

Dimensions:

120 x 80 x 60 cm (100 kits) 120 x 80 x 80 cm (150 kits)

Volume:

576,000 cm³ (100 kits) 768,000 cm³ (150 kits)

Weight:

Storage Conditions

- Storage temperature: 2-27°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: **9–12 months**
- Disposal Methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

A built-in procedural control on the test device indicates that the test is functioning correctly. A pink/red band should always appear in the control window.

Indicators of Potential Quality Problems

- The presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Physical damage to shipping carton, inner box, or test kits
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided

- Timer or stopwatch
- Blood collection devices (i.e., lancets, capillary tubes/test tubes)

- Approximately U.S.\$1.15-2.25 per test
- Price varies according to the quantity being procured.







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JSE John Snow, Inc.

VIRONOSTIKA HIV UNI-FORM II PLUS O: ELISA TEST KIT

Brand and Manufacturer

■ Vironostika HIV Uni-Form II Plus O

■ **BioMérieux** 69280 Marcy l'Etoil France

> Tel: +33 (0) 47-887-2000 Fax: +33 (0) 47-887-2090 www.biomerieux.com

Kit Contents

- 192 test kit contains 2 plates of 96 tests.
- 576 test kit contains 6 plates of 96 tests.
- 12 strips per plate, each with 8 wells.
- Strips can be broken in half.
- Each kit contains sufficient control serum, specimen diluent, phosphate buffer concentrate, TMB solution, peroxide solution, and plate sealers.

Percent Accuracy

- Sensitivity: 99.6-100%
- Specificity: 97.6–100%

Types of Samples

Serum and plasma

Run Time of Test

2 hours and 4 minutes

Packaging Information

■ 192 or 576 tests per kit

Test Kit Package

Dimensions:

27 x 23.5 x 6.6 cm (192 tests) 27 x 23.5 x 9.6 cm (576 tests)

Volume:

3,948 cm³ (192 tests) 6,027.75 cm³ (576 tests)

Weight:

Shipping Carton

Dimensions:

Volume:

Weight:

Storage Conditions

- Storage temperature: 2-8°C
- Allow the reagents, samples, and foil test pack to come to room temperature (18-25°C) before testing.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

Shelf Life and Disposal

- Shelf life: 12 months
- Disposal Methods:
 - Autoclave @ 121°C for 60 minutes
 - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control

■ 4-5 per test run

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided

- Washer
- Incubator
- Vortex mixer
- Microshaker
- Spectrophotometric reader
- Dispensing system and/or disposable tip pipettes
- Distilled/deionized water
- Sulfuric acid
- Disinfectant
- Absorbent tissue
- Disposable gloves
- Timer
- Reagent trough
- Disposable vial
- Biohazard waste containers

- Approximately U.S.\$0.75-1.56 per test
- Price varies depending on the quantity being procured.

